

# MAINTAINING U.S. GOVERNMENT BUSINESS OPERATIONS WITHIN THE NATIONAL CAPITAL REGION AFTER AN AEROSOLIZED ANTHRAX ATTACK

BY

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## **ABSTRACT**

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This paper evaluates countermeasure options available and recommends a strategic course of action of how the USG should posture its preparedness to minimize the effects of an aerosolized anthrax attack on its NCR Federal workforce in order to return to normal business operations as expeditiously as possible.





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## MAINTAINING U.S. GOVERNMENT BUSINESS OPERATIONS WITHIN THE NATIONAL CAPITAL REGION AFTER AN AEROSOLIZED ANTHRAX ATTACK

*"Bioterrorism is a real threat to our country. It's a threat to every nation that loves freedom. Terrorist groups seek biological weapons; we know some rogue states already have them....It's important that we confront these real threats to our country and prepare for future emergencies."*

President George W. Bush, June 12, 2002

### INTRODUCTION

The United States Government (USG) is nearly a three trillion dollar a year business which manages the day-to-day operations of this country.<sup>1</sup> The federal budget not only drives the financial system of the country as a whole, but is the focal point of the Washington, DC metropolitan area economy. In order to effectively conduct normal USG business operations, the USG employs 340,000 people throughout 231 federal departments and agencies within the area known as the National Capital Region (NCR).<sup>2</sup> The USG could not function without this dedicated federal workforce.

Anthrax as a bioterrorism weapon gives terrorists a variety of negative effects such as creating an immense amount of mortality and morbidity, denying the use of an area until proven safe, imprinting indelible marks on the American psyche, and triggering an enormous and intensive response and recovery. If a terrorist conducted an aerosolized anthrax attack over downtown Washington, DC, is the federal government ready to respond? The answer may be yes and no. Yes, the USG has mechanisms in place, such as the Continuity of Operations Plan (COOP) on how to maintain mission essential functions during a crisis. No, because the COOP only addresses the "must do" tasks during the crisis and does not provide a road map for enabling the Federal workforce to foster a return to pre-event business operations. The Federal workforce and conducting USG operations go hand-in-hand, so a countermeasure dispensing

plan is key to protecting this human capital after a large scale anthrax attack. If the NCR Federal employees are not able to return to the workplace safely, because they and their families are not adequately protected from anthrax, the country would become temporarily paralyzed, if not permanently crippled.

Just as companies have business continuity plans to operate during a crisis and effectively recover from it, the federal government must also conduct the same type of planning to address maintaining functions in the face of a biological event that requires countermeasure distribution. Unlike other bioterrorism agents, the swiftness of the antibiotic dispensing directly impacts the ability to protect the populace, to include Federal employees, as the effects of an aerosolized anthrax attack will be felt almost immediately.

The bottom line is that an aerosolized anthrax attack within the NCR presents a unique response problem that needs to be addressed separately from other response plans, due to the unparalleled characteristic of the high concentration of federal facilities. The only way to quickly and successfully restore regular operations is to plan now with the emphasis on how to protect the Federal workforce and their families.

The purpose of this paper is to conduct an analysis of the USG capabilities to protect the Federal workforce from being casualties of an aerosolized anthrax attack within the NCR in order to reestablish normal business operations as quickly as possible. The analysis included detection methodologies, command and control structures, typically accepted mass prophylaxis strategies, and suggested alternative countermeasure strategies. The analysis generated conclusions and recommendations which address the necessity and feasibility for the NCR Federal workforce to institutionalize a separate countermeasures program to ensure expedited reestablishment of USG business operations after an aerosolized anthrax attack.

## BACKGROUND

In order to better understand the effects of an aerosolized anthrax within the NCR, this section provides pertinent information on the characteristics of anthrax, its effects and use as a biological weapon. Also, demographic data on the NCR is discussed which demonstrates why this region is a prime terrorist target.

### Characteristics of Anthrax

Anthrax is a bacterial disease caused by *Bacillus Anthracis*, a gram-positive, spore-forming, encapsulated, nonmotile rod.<sup>3</sup> The spores can be found in many parts of the world. Anthrax occurs in three clinical forms: cutaneous, gastrointestinal, and inhalation. For the purposes of this paper inhalation anthrax is the only pathway of concern.

Inhalation anthrax occurs when enough spores have accumulated and germinated within the lungs and the bacteria releases toxins that have potentially lethal affects when the body's natural defenses are overcome. An exact mortality rate is not known; however, mortality estimates for untreated inhalation anthrax usually are anticipated to be greater than 80%.<sup>4</sup>

Normally, Inhalation anthrax has a short incubation period, usually a few hours up to 2-6 days depending on the initial dose received and the strength of the immune system of the infected person. More recent data shows the incubation period of 1-43 days.<sup>5</sup> In cases of a large infective dose, the incubation period is shorter. However, some suggest that incubation could take as long as several months based on spore dormancy and slow clearance from the lungs.<sup>6</sup> Primate data has shown that 2,500-55,000 inhaled *Bacillus anthracis* spores achieves a LD<sub>50</sub>.<sup>7</sup> A LD<sub>50</sub> (Lethal Dose 50) means a dose of a substance that produces death in 50 percent of a population. For anthrax, primate LD<sub>50</sub> data is used to estimate human reaction. Extrapolating to the lower end of the curve suggests that as few as 1-3 spores could be enough for a lethal

infection.<sup>8</sup> This low infective dose presents significant problems if re-aerosolization of spores occurs as it increases the potential for infecting family members of Federal employees.

Additionally, modeling of an anthrax attack on a metropolitan area has shown that the risk of mortality increases significantly as the time increases between the time of exposure and the time prophylaxis begins.<sup>9</sup> The short incubation period and the increase in mortality based on the time between exposure and prophylaxis support the rationale that mass prophylaxis must occur within 48 hours.

As a spore, anthrax is very resilient and persists for a long time in the tissue of the lungs or in the environment. Contaminated surfaces, such as federal office buildings, are expensive to decontaminate and the duration of the operation may be considerable, which would limit recovery and reconstitution of government functions. Business operations, whether government or private, could be negatively affected impacting the long-term financial health of the organizations or the economy as a whole

#### Anthrax as a Weapon

In 1972, the “Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological and Toxin Weapons and on their Destruction” (also called the Biological Weapons Convention)<sup>10</sup> was created to prohibit the countries from developing biological weapons. The document was eventually signed and ratified by 103 nations, to include the United States and the Russian Federation on March 26, 1975.

The prohibition did not prevent the Russian Federation from secretly continuing their biowarfare program. The city of Sverdlosk (now Yekaterinburg) is located about 900 miles east of Moscow, Russia. On or about April 2, 1979, Compound 19, a military biological weapons facility, had an accidental release of anthrax spores due to mishaps surrounding the replacement

of a clogged filter. Subsequently, several reports of the outbreak occurred, but it was covered up with a fabricated story of contaminated beef.<sup>11</sup> After Russia President Boris Yeltsin acknowledged in 1992 that the KGB had been operating a BW facility, he allowed Dr. Matthew Meselson, a Harvard Professor, and a team of experts to collect and analyze epidemiological data from the event. Dr. Meselson estimated 77 people were infected and 66 died.<sup>12</sup> These numbers are lower than the numbers reported by others. Dr. Ken Alibek who is a former First Deputy Director of Biopreparat (a secret organization overseeing Russia's BW program) puts the death toll at 105, but could be much more.<sup>13</sup>

Despite the international prohibition of state-sponsored bioweapons programs, there continues to be interest in anthrax as a mechanism for terrorism. During the 1980s and 1990s, several groups from religious cults, white supremacists, and terrorist organizations have tried to obtain and/or disseminate several different types of biological agents. These planned and/or executed attacks validate that biological agent development is still occurring. Significant events with regard to anthrax include: Iraqi General Hussein Kamal Hassan, a defector, reported in 1995 that Iraq had an arsenal of weaponized anthrax in bombs, rockets, and warheads; Aum Shinrikyo sprayed anthrax from a Tokyo building top in 1993; and an individual threatened to release anthrax in Las Vegas, but the strain in his possession was harmless. In 1999, the United States had 81 anthrax threats, most of which were hoaxes.<sup>14</sup>

The capabilities to make or acquire weapons grade anthrax and then deliver it effectively aren't easy tasks. However, in November 1997, the Director of the United States Arms Control and Disarmament Agency (ACDA) stated that as many as twelve countries have viable offensive biological weapons programs in direct violation of the Biological Weapons Convention.<sup>15</sup> Three of these (Syria, Iran, and North Korea) are also listed by the Department of State as "State

Sponsors of International Terrorism”.<sup>16</sup> This data suggests that terrorists have the means necessary to conduct a successful attack against the US.

For the United States the anthrax bioterrorism threat changed to reality in 2001. Anthrax laden mail infected twenty-two people in five states. Naturally occurring anthrax spores vary in diameter, clump due to moisture, and usually are found in low concentrations. The envelopes in 2001 had optimum particle size for capture within the lungs and had coatings to prevent clumping which allowed the spores to maintain their optimum diameter which are characteristics of weapons grade anthrax. These distinctive qualities suggest the terrorist had sophisticated scientific training and equipment or access to a supplier.<sup>17</sup>

The attack resulted in eleven cases of inhalation anthrax and eleven (7 confirmed, 4 suspected) cutaneous infections. Of the eleven inhalation cases, five died. No deaths occurred from the cutaneous cases. Even with receiving antibiotic treatments, the mortality rate for inhalation anthrax was 45%.<sup>18</sup> Although this figure is somewhat misleading, in that one individual did not have a timely diagnosis and another was elderly.

The 2001 terrorism incidents not only cost American lives, it generated an immense monetary toll. The General Accounting Office reported that the havoc wreaked on the United States economy totaled \$191 billion dollars and continues to grow.<sup>19</sup> The USG came to a virtual standstill resulting in cessation of normal business operations as departments and agencies scrambled to ensure the safety and security of their organizations. However, restart of operations proceeded very slowly as the USG had to adapt to the “new normal” environment where government operations at every level changed to address security and safety vulnerabilities. This adjustment to the “new normal” environment is still ongoing and planning efforts are turning to agent-specific scenarios.



In the six plus years since the event, major insurers, airlines, and tourism have all been economically impaired.<sup>20</sup> The USG has spent hundreds of billions of dollars to protect the American public from more terrorist events, to include establishing the Department of Homeland Security (DHS) to oversee the USG ability to deter, prevent and respond to an incident.

#### National Capital Region (NCR)

As a worldwide symbol of political freedom, capitalistic economics, military might (Pentagon), and enduring prosperity, the NCR is beacon of hope for a better future for some and to a few, an evil pariah. In 2001, terrorists demonstrated they view the Washington, DC metropolitan area as a primary target with the crashing of American Flight 77 into the Pentagon; the anthrax laden envelopes sent to two US Senators, and the thwarted attack of terrorists crashing United Airlines Flight 93 into the US Capitol Building. In order to better understand the value terrorists put on the NCR as a target, it is important to understand the area.

The National Capital Planning Act of 1952 established the NCR as an entity to include the following areas to their outer boundaries: the District of Columbia, the Maryland counties Montgomery and Prince George's, and the Virginia counties of Prince William, Loudon, Fairfax, and Arlington. Any city within the NCR boundaries at that time or in the future would also be included in the NCR.<sup>21</sup> The NCR was redefined by legislation in 2004 to include those counties with a border abutting the previously defined NCR area and any municipalities therein.<sup>22</sup> This legislation recognizes the significant percentage of the Federal and civilian workforce that reside outside the established NCR boundaries.

According to the U.S. Census Bureau data from 2000, almost 4.2 million people live in the Washington, DC metropolitan area which ranked fourth nationally and covers over 6,000 square miles.<sup>23</sup> The population significantly increased from 2000-2005, as the present Census

Bureau statistics show that the Washington, DC metropolitan area neared 5.3 million<sup>24</sup> with 65% of normal working age (18-64 years old).<sup>25</sup> This translates into one out of every ten NCR employees is a Federal worker. Also, the local jurisdictions must account for a limited mobile population in their response planning as 25% are under 18 and 10% over 65. The NCR serves as a major transportation hub as it is supported by two major international airports and the second largest rail transit system.

The NCR maintains the core of our federal government with all three branches located within its boundaries. With 231 federal departments and agencies located here, there are 340,000 Federal workers employed within the NCR. It is estimated that over 20 million visitors per year come to see the historic, cultural, governmental and other events within the NCR. Many large corporations, philanthropic and non-profit organizations, international finance institutions, and universities are located there. These economic mainstays coupled with the state and local governments and businesses makes the NCR an economic powerhouse as it is ranked fourth nationally in Gross Regional Product.<sup>26</sup>

If a widespread anthrax attack occurred in the NCR, based on the recent US Census Bureau estimate, 5.3 million people may require mass prophylaxis with antibiotics. The current USG ability to protect the NCR Federal workforce (6.5% of the regional population not including family members) from an aerosolized anthrax attack is minimal. Currently, the USG response relies on early detection, command and control structures, and typically accepted anthrax response strategies. However, these response strategies have limitations.

This paper explores these strategies and identifies some alternatives that address existing limitations in the USG's ability to protect the NCR Federal employees in the event of a large scale anthrax attack in the NCR. Specific strategic recommendations are offered on how to

maximize the protection of the Federal workforce and ensure expedited reestablishment of USG business operations as rapidly as possible.

## **EARLY DETECTION**

The most efficient method to counteract the devastating human effects of an aerosolized anthrax attack is to identify that an incident has occurred as early as possible after the event. Mechanisms exist to assist public health officials to recognize that an anthrax attack has occurred, but no real-time detection is possible at this time. There are two methods of early detection: environmental sampling and biosurveillance.

### Environmental Sampling

The President's 2003 State of the Union Address focused on combating bioterrorism and announced that the DHS would be deploying an early warning network to detect a biological attack.<sup>27</sup> The new system, BioWatch, was deployed to several cities to include Washington, DC.<sup>28</sup> BioWatch is a mechanism to test for airborne pathogens to include anthrax. BioWatch's early warning and identification mechanisms are intended to provide public health officials the information they need to make critical decisions, such as the need for mass prophylaxis, to increase the efficacy of the response.

BioWatch's success depends on three main elements working in harmony. The first element rests with the Environmental Protection Agency (EPA) whose responsibilities include, setting up the BioWatch equipment at pre-designated sampling sites; collecting samples every 24 hours; and transportation of the samples to a laboratory for analysis. The second element is analysis of the samples. The CDC, in conjunction with its federal, state, and local partners developed the Laboratory Response Network (LRN). Utilizing a consensus protocol and polymerase chain reaction (PCR) technology, this network can perform presumptive and

confirmatory tests. Prompt analyses and subsequent identification can reduce the amount of time it takes to recognize an attack has occurred. The Federal Bureau of Investigation (FBI) is responsible for the third element of the BioWatch program which is the law enforcement actions associated with an attack.<sup>29</sup> The aforementioned description of BioWatch is now called Gen 1 (for 1<sup>st</sup> generation).

BioWatch is federally funded, but locally operated. Since the local jurisdiction is responsible for response decision making, a jurisdiction could be moving forward on a response, prior to notifying the federal government of the positive results. Delayed reporting could slow federal support or lead to indecision. Good prior planning in the NCR has led to a protocol of speeding information sharing and decision making between local and federal entities.

Even though the system can be effective, it is not real-time monitoring. For example, if an aerosolized anthrax attack occurred at noon near the National Mall on a warm spring work day, there would be thousands of people outside enjoying the weather and over 300,000 Federal workers at or near their places of employment. Depending when the sample is collected; it could be well into the next day before presumptive results are available. The time it takes to sample, analyze, and make a decision could take up to 24 hours after the release which decreases the time to provide prophylaxis to those potentially infected before onset of symptoms.

During fiscal years 2005-2007, Biowatch Generation 2 (Gen 2) increased the number of sensors in ten high threat cities and provided mobile units for selected critical facilities, transportation hubs, and for special events. Currently, BioWatch is deployed in over thirty metropolitan areas, which has enhanced detection capabilities; however, there are still many other large cities and metropolitan areas that are unmonitored and highly susceptible to an unrecognized anthrax attack. Even BioWatch cities have limited coverage which may cause a

release to go undetected. If the premise is “something is better than nothing,” than we have achieved “something.”

This BioWatch Gen 2 improved coverage in some areas, but didn’t increase efficiency in time for obtaining results. Presently, real-time detection of an aerosolized anthrax attack is not possible. BioWatch’s lag time between incident and positive results is 6-30 hours. When coupled with the 12-24 hours it would take for delivery of countermeasures, this could put a large number of infected personnel at risk of increased morbidity and mortality. The present BioWatch system is adequate for other infectious agents that have a longer incubation period. With its shorter incubation period, anthrax should be the focus of development for real-time detection capabilities. It may be costlier in the short-term to develop and field an agent-specific detection system, but the long-term benefits in saving lives and returning to normal business operations in the affected area is invaluable.

BioWatch’s Gen 3 future priorities include developing a real-time, integrated detection system; delineating the chain of authority; increasing the coordination between states and federal authorities to streamline assistance and improve consistency of response; and standardize protocols for handling of positive results. These measures should increase the effectiveness of the detection, standardize notification and reporting, and shorten the response time. Two potential prototype systems that conduct near-real time analysis (1-2 hours) and wirelessly transmit results to the local public health laboratory are being evaluated for use with preliminary results expected this year.

Two other environmental surveillance programs, Guardian Shield and Pentagon Shield, conduct aerosol monitoring against threat agents. However, at this time these Department of Defense programs are independent of BioWatch and don’t have a mechanism to readily share

their results with local jurisdictions. An important strategic enhancement to the environmental sampling program would be to integrate these separate programs in order to afford greater coverage of the NCR against aerosolized threats and integrate communication protocols for timely information exchange to expedite the response.

### Biosurveillance

The other mechanism for early recognition that a bioterrorism act has occurred is biosurveillance. Biosurveillance has received a lot of attention culminating in 2004 when the DHS was assigned the responsibility to develop a national biosurveillance program by collaborating with stakeholders in the federal, state, and local governments.

Biosurveillance is a passive mechanism for disease outbreak identification in most public health departments. Passive systems are retroactive evaluation of symptoms and/or diagnoses looking for commonalities that show a trend. Data is collected from patients showing up in hospitals, clinics, and other healthcare facilities. The data is compiled and analyzed either electronically or manually to identify possible causalities. Many factors can affect how quickly an outbreak is identified through biosurveillance, such as the location and size of the pathogen release, disease incubation time, symptomatology, and the number of infected people reporting to a facility that is part of the data collection network.

Biosurveillance systems are less effective with diseases that are aggressive, initially appear as common cold symptoms, and have a short incubation time like anthrax. Thus biosurveillance is a less effective method of recognizing that an anthrax attack has occurred.

Since 1999, several civilian and military health care facilities throughout the NCR use a biosurveillance computer program called ESSENCE II (Electronic Surveillance System for Early Notification of Community Epidemics) to track traditional and non-traditional epidemiological

data to identify trends and possible outbreaks. ESSENCE II does provide near real-time data analysis. However, since it is not used comprehensively and at all levels of health-care, the data can be sporadic or not even captured if patients go to providers that are not part of the ESSENCE II network.

Another biosurveillance system, BioSense, is operated by the Centers for Disease Control & Prevention (CDC). As of April 2007, BioSense has 366 facilities covering 46 major metropolitan areas and 37 states transmitting real-time data to BioSense integrators at local and state health departments.<sup>30</sup> The information is reviewed by health officials and the integrators then transmit the data to the CDC. Also, BioSense collects and analyzes data from Department of Veterans Affairs, Department of Defense, and other medical entities on a daily basis for analysis. The primary objective is to expedite recognition and response through sharing of syndromic data (a group of symptoms that collectively indicate or characterize a disease) which is analyzed for anomalies at the CDC BioIntelligence Center (BIC). The time for the data to reach the health departments varies as each facility may transmit the data on different schedules. Once the data reaches the Biosense integrator it is available for evaluation by the CDC. BioSense has a BioPHusion section whose personnel analyze the collective data from all the jurisdictions to identify anomalies and subsequently work with local and state health officials to offer feedback on potential outbreaks and share information on surrounding health districts.

ESSENCE II has distinct advantages over the national BioSense system with respect to an anthrax attack within the NCR. First, ESSENCE II is regionalized and has a greater concentration of data sources in the NCR to allow for more definitive findings. Second, epidemiologists at the local, district, and state health departments via ESSENCE II use methods

to continually analyze data both for temporal and geospatial anomalies, and they work with regional public health officials on possible interventions.

DHS is working to connect data from BioWatch, BioSense, and intelligence sources to form a single surveillance system. Combining environmental and syndromic surveillance data provides an integrated snapshot of an area with respect to a possible agent release. This approach in the NCR will greatly enhance the response capability to anthrax as a clearer picture of the release can be visualized and adjustments to the response can be executed.

## **COMMAND & CONTROL**

Responding to an anthrax attack in the NCR would pose unique challenges for command and control because of the interface of local, state and federal tiers of government. These challenges are particularly worrisome since timely response is required to prevent morbidity and mortality following an anthrax attack. The following sections provide information on how the different levels of government would interface for an anthrax response.

### State and Local Jurisdictions

The State of Maryland, the Commonwealth of Virginia, and the District of Columbia have established plans to respond to many types of emergencies, to include bioterrorism response. These plans designate who is in charge within their jurisdiction depending on the type of incident. Each jurisdiction knows their responsibilities and makes decisions based on available information.

Counties and cities within Maryland and Virginia generated emergency response plans which have been vetted with their respective state emergency management agencies to maintain continuity throughout the area response. In the NCR, jurisdictions have been provided federal funding and planning support to create anthrax-specific response plans.<sup>31</sup> These emergency plans



are useful for a local and/or state response but they don't necessarily address the complexities of the NCR multi-jurisdictional response.

### Regional Organization and Planning

The Metropolitan Washington Council of Governments (MWCOG) was organized by the NCR jurisdictions, to include state representatives, to collaborate and plan a broad spectrum of regional issues, such as the environment, transportation, homeland security, and emergency response. The MWCOG addresses particular issues through committees with some having Federal representatives interjecting the USG perspective. The MWCOG's BioEmergency Subcommittee and Dispensing Workgroup (BESDW) conducts bioterrorism response planning. The BESDW ensures good continuity of effort for a regional response. The BESDW conducted extensive work on a large scale anthrax response for the NCR, in the areas of developing common forms and public messaging, planning and locating Points of Distribution (discussed later), and cross-leveling of support.

Even though the local, state, and regional governmental authorities have viable anthrax mass prophylaxis plans, limited integration with federal government planning or local federal facilities potentially limits the effectiveness of the overall response.

### Federal Structure

Homeland Security Presidential Directive-20 establishes a comprehensive national continuity policy for maintaining critical federal government structure and operations during a national emergency. The USG Continuity of Operations Program (COOP) plan requires each federal agency to facilitate their agency's response to an incident.<sup>32</sup> However, this policy only supports each organization's capability to conduct mission essential functions to respond to the emergency at pre-designated alternate locations. Even though this allows for governmental

management and response functions to be continued, it does not address a return to normal business operations. Basically, the COOP is a logistical plan to move government entities to a protected location to conduct critical functions. Also, the COOP only addresses the protection of the pre-identified essential personnel involved in the move to an alternate location, but does not specifically address where and how countermeasures will be provided for those personnel.

On March 22, 2008 the National Response Framework (NRF) replaced the National Response Plan as the document outlining the comprehensive, national, all-hazards response to a domestic incident. It describes how federal, state, local and non-governmental agencies will provide an integrated response to maximize effectiveness. The roles, responsibilities, and principles for each level of government are identified within the NRF.<sup>33</sup>

A Biological Incident Annex is contained within the NRF. This annex provides general planning assumptions, operational concepts, and required actions, but does so very generically due to the diverse types of biological events and the complexities of each specific disease. Anthrax is atypical compared to other threat agents due to the accelerated response required, so a one-size fits all approach is not viable.

Federal Emergency Management Agency (FEMA) Region III conducts the federal emergency response planning and execution for the NCR from the offices in Philadelphia, Pennsylvania. FEMA Region III provides a regional response approach across its entire area of responsibility. However, accounting for the NCR federal entities and their employees after an anthrax attack is not specifically addressed in planning. During an NCR crisis, it is possible that the National Response Coordination Center in FEMA headquarters may become the focal point for execution.

After the formation of the Department of Homeland Security (DHS) in 2002, Congress directed DHS to enhance the emergency response coordination within the NCR. In March 2003, the DHS established the Office of National Capital Region Coordination (NCRC) to provide oversight and coordination of federal programs with State, District, local, and other regional authorities.

The NCRC has become a conduit of information flow and has reached out to governmental and some non-governmental organizations to develop integrated plans. Many of the state and local representatives who serve on regional planning committees, such as BEDSW, work with their federal partners through the NCRC. Presently, the NCRC continues coordination efforts, information sharing, and collaborative planning. However, the NCRC is not a decision-making entity for the federal response as that responsibility still lies with FEMA Region III.

#### NCR Response Planning and Decision-Making

The state and local authorities have well-defined and well-coordinated anthrax response plans that they continue to improve. The cooperation across these jurisdictions increases information sharing and ultimately decision-making. The jurisdictions have actively engaged some federal facilities to be incorporated into their anthrax response plans for mass prophylaxis. However, this only targets individual facilities and doesn't address all Federal employees working within their jurisdictions.

State and local representatives want to know "What is the federal plan?" as this affects their response execution. At the present time, it is unclear with respect to an anthrax response if and how the NCR Federal workforce and their families will receive mass prophylaxis. Currently there are several initiatives to provide mass prophylaxis to the population. The next two sections

will discuss typical and alternate strategies for mass prophylaxis and why they may or may not work for NCR Federal employees.

## **TYPICAL STRATEGIES**

Over the last few years, the federal government has created new programs or refined existing ones to increase the effectiveness of the state and local response to an anthrax attack. As discussed previously, modeling has shown that dispensing of antibiotics for post-exposure prophylaxis after an aerosolized anthrax attack must occur within 48 hours to effectively protect the people in the targeted area.<sup>34</sup>

The Food and Drug Administration (FDA) approved post-exposure prophylaxis requiring a 60-day regimen of antibiotics to ensure full protection according to the Centers for Disease Control and Prevention (CDC).<sup>35</sup> The two antibiotics that are most effective and most often stockpiled are doxycycline (doxy) and ciprofloxacin (cipro).<sup>36</sup> Other antibiotics may be used, but doxy and cipro are relatively inexpensive and readily available. Also, the two pills per day for doxy and cipro lessens the logistical burden for movement and dispensing and lessens the number of doses the recipient is required to take daily. The programs to provide prophylaxis in response to an aerosolized anthrax attack include the Cities Readiness Initiative (CRI), Out-Sourcing and the Strategic National Stockpile (SNS).

### Cities Readiness Initiative

The CRI assists major U.S. cities and metropolitan areas to respond to a massive anthrax attack. The focus is to assist these cities in strengthening their planning and response capabilities, especially as it relates to the “how to” of mass prophylaxis operations. The CRI jurisdictions received federal funding to prepare for dispersing antibiotics to the populace within 48 hours of the decision to do so.<sup>37</sup> Through 2007, the CRI funded 72 cities to upgrade their mass

prophylaxis plan and capabilities to ensure 100% of the affected population is able to receive their medications within the 48-hour window.

Washington, DC, as well as New York City and Los Angeles, receive direct funding. These cities were identified as high-value terrorist targets based on risk factors based on being economic centers, seats of government, historical sites, and having a high population density. Jurisdictions conducting mass prophylaxis operations can do so using a variety of scalable distribution methods. The program stresses the use of community-based caches of antibiotics; Points of Dispensing (PODs) to prophylaxis the populace at pre-designated locations; and home delivery of medications by the United States Postal Service (USPS) to those that may be unable or unwilling to leave their homes.

Several state and local governments maintain caches of pharmaceuticals to respond quickly to a threat or an event. In most cases, these caches have been established locally or through federal funding such as CRI, but they usually only meet the immediate need of protecting a small portion of the population that is critical to the overall response, such as emergency services personnel, governmental decision makers, and health care workers. These caches are usually pre-positioned within the healthcare infrastructure to ensure that the emergency can be addressed immediately at the local level.

The PODs are pre-designated areas, such as schools, auditoriums, and other public buildings that are suitable for conducting mass prophylaxis operations. The CRI gives guidance to the covered jurisdictions about how to establish a POD and what personnel, equipment, and procedures are required to organize an effective mass prophylaxis site.

The USPS concept is to ensure the widest coverage of residents by bringing the antibiotics to them. The concept ensures residents with limited mobility or transportation receive

their medications. Home-delivery minimizes the amount of resident movement, reducing impediments to emergency services vehicles supporting the response and potential spread of spores. This method puts a tremendous logistical burden on the USPS to carry out delivery and there is no guarantee that 100% of residents will receive their antibiotics. However, the USPS, in conjunction with DHHS, successfully conducted three operational drills in Seattle, Philadelphia, and Boston delivering antibiotics to 38,000, 52,000, and 23,000 residences, respectively.<sup>38</sup> Roadblocks for this option exist, particularly how to protect postal carriers from potential exposure to anthrax spores while they are delivering the antibiotics. The FDA raised concerns about giving the carrier pre-packaged antibiotics for their self-protection, such as the MedKit (discussed later). This is an off-label use which classifies the antibiotics as “new drugs” and subject to certain regulations. Also, the Occupational and Safety Health Administration must determine what workplace protection requirements apply to this situation.<sup>39</sup>

The CRI increases local jurisdictions’ readiness for an anthrax response through local planning and execution. However, it does not address how to provide prophylaxis in areas with large concentrations of Federal employees, such as the NCR since the POD and USPS concepts are based on where people live. Thus there is no mechanism to provide mass prophylaxis for Federal workers at their place of employment.

### Out-Sourcing

Some local jurisdictions have taken novel approaches to addressing shortfalls in their mass prophylaxis plans such as looking to integrate the corporate community into their response networks.

The Commonwealth of Virginia contracts with United Parcel Service (UPS) to transport countermeasures from their distribution point to their PODs. This type of community

involvement significantly decreases the overwhelming logistical burden on the state and local governments.

Also, some jurisdictions are looking to partner with companies or pharmacy chains to serve as PODs. Jurisdictions are discussing with Wal-Mart, Home Depot, and CVS Pharmacy the possibilities of these stores serving as PODs. Attractive as this approach may be, significant issues such as POD security and dispenser liability need to be addressed to solidify this type of relationship.

### Strategic National Stockpile

The local caches for mass prophylaxis will not be sufficient to meet the needs in a large scale anthrax attack. The HHS Strategic National Stockpile (SNS) has twelve stockpiles that contain over 300,000 ten-day regimens of antibiotics (cipro and doxy) in adult doses geographically dispersed throughout the country. However, most major metropolitan areas contain well over a million people, so depending on the size of the event, the SNS stockpile may not be sufficient to supplement state/local caches. If more antibiotics are required, the SNS can activate its Vendor Managed Inventory (VMI). The VMI provides agent-specific support directly from the pharmaceutical contractor's warehouse to the requesting jurisdictions' locations. In the case of anthrax, VMI can deliver significant quantities of doxy and cipro for mass prophylaxis within 12-36 hours of notification. VMI will be the primary source for supplying the affected region with antibiotics for mass prophylaxis.

A potential problem with storing and maintaining antibiotics in sizable stockpiles exists when the cached pharmaceuticals near their shelf life expiration. VMI helps limit loss due to expiring medical materials. Also, through compliance with the Shelf Life Extension Program (SLEP), federally-funded stockpiles can obtain extended holding times.

The SLRP was started in 1986 to assist DOD in managing their pre-positioned stocks or war reserves.<sup>40</sup> In conjunction with the Food and Drug Administration (FDA), the program evaluates a sample of stored medical material and determines if a shelf life extension is warranted. The program proved very successful. Testing over several years has led to several shelf life extensions, to include antibiotics used for prophylaxis against anthrax. Cipro went from originally having three years of shelf-life to as many as 13 years and doxy went from two to seven years for the war reserves.<sup>41</sup> This program translated well for use with the SNS. Since the SNS is maintained in climate-controlled environment like the DOD war reserves, it utilizes the SLEP to extend the shelf life of the same anthrax countermeasures. As an example, the SNS shelf life of cipro has been extended 7-9 years.<sup>42</sup>

## **ALTERNATIVE STRATEGIES**

Depending on the size of the event and the population affected, the current CRI mechanisms may be insufficient to meet the needs of the jurisdictions within the NCR, let alone meet the needs for the Federal workforce. Alternative strategies are being explored. These strategies include keeping antibiotics in the home (Medkits), use of an anthrax vaccine, and Closed or Federal Points of Dispensing.

### Emergency MedKit Evaluation Study

The MedKit is a home-based kit which contains the antibiotics, doxy and cipro, for anthrax post-exposure prophylaxis. This study, which was conducted in the St. Louis, Missouri metropolitan area by the CDC, evaluated whether normal households could properly store and maintain the MedKits for the duration of the study period. The outcome was to provide data to policy makers on the feasibility of the MedKit as a home-based prophylaxis mechanism.<sup>43</sup>



The study included over 4250 households looking at a variety of different variables, such as maintaining the kit as directed and behaviors that may affect the proper use or storage. The study data created a baseline to determine if the Medkit program was a viable alternative to the existing CRI initiatives. Since the antibiotics were distributed for post-exposure prophylaxis prior to an event occurring which is not an approved use, the Food and Drug Administration (FDA) labeled this as an Investigational New Drug (IND).

The study demonstrated that the participating households were able to maintain the MedKits as directed. This study confirmed the concept of home-based prophylaxis to be feasible as a method of reducing the logistical burden of mass dispensing of antibiotics and assists in achieving the goal of providing mass prophylaxis within 48 hours. However, if an anthrax event occurred in a nearby city, the possibility does exist that they could take their medications erroneously.

The results of this study could have far-reaching implications on the feasibility of protecting the NCR Federal workforce and their families immediately after an event. If the anthrax attack occurred near the National Mall in Washington, DC during working hours, it could potentially expose and subsequently infect tens of thousands Federal employees. If a MedKit with a 5-day supply of antibiotics for the employee and each family member was authorized and pre-dispensed to be maintained at their residence (alternate mechanisms for workplace dispensing will be discussed later), the advantages outweigh the cost. Some benefits include: taking a portion of the initial dispensing burden off local jurisdictions; increasing the probability of key and emergency response personnel returning to their duties to address the crisis; assuring the Federal employee that the family is taken care of prior to returning to their place of work; and most importantly, the protection of human life. Also, this would encourage

those Federal employees who support non-emergency functions to return to their duties sooner easing return to normal business operations and potentially limiting the long-term effects on the USG.

However, shelf-life can have limiting effects on the distribution of prophylaxis to individuals in the form of MedKits. Since the assumption has to be made that issued MedKits would not be kept constantly in the required environmental conditions, extending the shelf life is not feasible. Consideration must be given to shelf life if the MedKit concept moves forward as an operational reality.

#### Vaccines for Anthrax.

In addition to antibiotics, the other approved countermeasure for inhalation anthrax is anthrax vaccine adsorbed (AVA) for pre-exposure prophylaxis. AVA is an inactivated cell-free product that has been U.S. licensed since 1970 and is delivered in a 6-dose series. The vaccine was produced primarily for high-risk users, such as workers handling animals or their carcasses. In 1997, all active-duty and reserve military personnel were mandated by Department of Defense (DOD) to receive the vaccine.

The Project BioShield Act of 2004 amended the Public Health Service Act to streamline countermeasure development procedures and subsequent approvals. The BioShield Act authorized \$5.6 billion dollars over ten years to purchase and stockpile drugs to prepare against the use of threat agents. The Act allows for expedited development of countermeasures, allows the FDA to permit use of promising treatments in emergency situations, and promotes the purchase of “next generation” medical countermeasures.<sup>44</sup>

The first contract under BioShield that was awarded in 2004 and was expected to produce 75 million doses of the “next-generation” of anthrax vaccine. The new vaccine was

attractive because it was anticipated to provide immunity after only three doses and was based on a recombinant form of a protective antigen. The contractor was not successful in the new vaccine development and the next generation of an anthrax vaccine failed to materialize. Since the creation of the next generation of vaccine was not successful, HHS purchased and stockpiled 18.75 million doses of AVA.<sup>45</sup>

An alternative strategy that should be considered is the use of AVA to protect the Federal workforce in a pre-event vaccine campaign. Using this approach for select NCR Federal employee groups, such as operation center personnel or responders, would decrease their vulnerability as the front line responders after an anthrax event in the NCR.

Another approach that could be considered to protect the Federal workforce is use of AVA for post-exposure prophylaxis in conjunction with antibiotic therapy. When FDA approves a pharmaceutical for use, it is for a specific purpose. The manufacturer must ensure the labeling as required under the Food, Drug and Cosmetic Act (FD&CA) of 1938 or subsequent amendments describes the proper dosage and use. If there is reason to use the medication “off-label” such as AVA for post-exposure prophylaxis, prior FDA approval must be given. At the time of the 2001 attacks, some investigators believed there was benefit to post-exposure prophylaxis with AVA for those individuals identified receiving a potentially high dose of spores. The 32,000 individuals identified with a potentially high risk of being exposed to anthrax in these attacks, were offered AVA close to the end of their 60 day regimen of antibiotic prophylaxis. It was given under Investigational New Drug procedures.<sup>46</sup> Of the 32,000 individuals suspected as being exposed from the different locations, no cumulative data could be located on how many accepted the AVA option.

However, a study of those presumed exposed in Senator Daschle's office at the Hart Office Building had 51 of 59 individuals accept the AVA. The author suggests that the combination of antibiotics and AVA post-exposure is highly immunogenic and may shorten the required antibiotic regimen.<sup>47</sup>

The Project BioShields Act of 2004 created Emergency Use Authority (EUA) by amending the FD&CA in a provision entitled Authorization for Medical Products for Use in Emergencies.<sup>48</sup> There are steps that are required to enact an EUA, but they can occur quickly. The most important of these steps with respect to countermeasures is the determination that the benefit outweighs the risk. If AVA were to be given as post-exposure prophylaxis, the new authorities would require an EUA, rather than an IND.

If a pre-event AVA program and home-based antibiotics are combined into a Federal workforce protection program, this program could help to assure that the business functions of the federal government are re-established more quickly following an anthrax attack. Processes for integrating this program into existing programs would be possible. For example, this program could be integrated with the SNS stock turnover to serve as the countermeasures supplier.

Even with the complex rules governing countermeasures, the system works with great efficiency. However, if a plan to protect the NCR Federal employees is to be effective, the mass prophylaxis plan must be able to integrate the diverse countermeasures programs and concepts to maximize the resources available while lessening the burden placed on the federal agencies required to manage the plan.

### “Closed” Point of Dispensing (C-POD)

A final potential strategy to protect the federal workforce and assure continuity of business for the federal government in the NCR is C-POD. A C-POD is a dispensing site that targets a specific group of the population, such as large employers, federal facilities, and universities. These potential C-PODs would receive a delivery or pick up their antibiotics from the servicing distribution center and staff their own POD at their location. The concept protects the organization’s workforce and provides a mechanism to get antibiotics to the employees’ families. This concept has possibilities for success, but presents the same security and liability limitations as out-sourcing for non-governmental entities.

However, a closed federal POD is a viable option due to the present security posture of NCR federal facilities and liability is less of an issue if the dispensing is conducted by Federal employees. The Office of Assistant Secretary for Preparedness and Response in the Department of Health and Human Services is developing a concept for federal PODs. The concept designs the operation of two types of PODs, medical and non-medical based on previous designs that were formulated in support of civilian PODs.

The non-medical POD model provides for the quick dispensing of antibiotic countermeasures with minimal amount of medical personnel involvement. The non-medical POD fits into the anthrax mass prophylaxis concept well, due to the accelerated pace of dispensing and the minimal medical review requirements. The non-medical POD will be only the concept discussed here. A federal POD could issue antibiotics for Federal employees and their family members.

The federal POD could issue antibiotics for Federal employees and their family members. However, with 231 federal departments in the NCR, timing becomes a potential obstacle. By the

time the decision is made to mass prophylaxis and adding the time for delivery of antibiotics to the federal PODs, many Federal employees may have vacated the area leaving only emergency essential personnel on-site. This time lag must be considered to ensure that antibiotics aren't being pushed to PODs who don't have any recipients.

Other obstacles exist which could affect the success of federal PODs. First, if each of the 231 federal organizations would have their own POD, the issues are the organization's ability to develop a feasible dispensing plan, staff the POD, and conduct dispensing operations quickly. Most government entities have multiple NCR locations which are not necessarily collocated which increases the difficulty to ensure their workforce receives their antibiotics. Secondly, waiting on VMI to furnish antibiotics from the contractor's warehouse to the distribution point and in turn, resourcing the PODs may be too long a time period as many Federal employees may be evacuating the area and the federal countermeasures requirement is competing with local jurisdictions' requests. In order to efficiently and swiftly distribute the countermeasures, a closer federal cache managed by the SNS should be evaluated to determine if this is a feasible option. Lastly, the federal government may appear as it is taking care of itself and not supporting the populace. This issue can be mitigated by transforming the federal POD into a local POD once the initial mission is completed. However, if the federal POD becomes a local POD, the federal POD should adhere to the WMCOG standardized countermeasures dispensing documentation and requirements which means more comprehensive planning is required.

Concepts that may be feasible include: area-based PODs which are responsible for dispensing to federal employees in certain geographic sectors, drive-through PODs located near major thoroughfares exiting the metropolitan area, and a combination of the different concepts. The federal POD option certainly requires further evaluation to determine which concept can

best accomplish the desired outcome. This may require the use of different concepts based on when the decision to mass prophylaxis occurs.

## **CONCLUSION**

If history has taught us anything, the use of anthrax as a weapon is both possible and deadly effective. The NCR is too vital an area to be incapacitated for a significant amount of time as the negative ramifications on the United States societal and economic health could be permanently damaged. The responsibility of the USG is governance of the country and the care of its people. In order to accomplish this, the USG must maintain its human capital to revitalize NCR government operations effectively.

The bottom line is that presently the National Capital Region Federal workforce is not specifically accounted for in any jurisdictional response plans with regard to mass prophylaxis after an aerosolized anthrax attack, potentially endangering the health of the USG employees and their families. Some Federal employees are NCR residents which means they are accounted for in local plans; although many don't live in the NCR, so there is definitely a gap in the planning.

Of the several typical and alternative strategies discussed, there is not a single dispensing method or countermeasure program that will achieve maximum results. The NCR Federal workforce is too numerous and widespread for an individual option, so a risk-based, multi-pronged approach should be developed.

With the purpose of providing an effective response and returning to normal business operation as soon as possible, Federal employees must be able to return to their duties with the confidence that they and their families are protected. Having Federal employees seek prophylaxis at local jurisdiction POD can only exacerbate the situation by seriously slowing down a response and the hopes of any return to normalcy. The operational strategies outlined in

this paper for providing countermeasures to the Federal workforce have strategic ramifications. Also, these strategies will decrease the burden on the local jurisdiction and promote the early return to normal government business functions.

## **STRATEGIC RECOMMENDATIONS**

A risk-based, multi-pronged approach can effectively protect the NCR Federal workforce from the effects of aerosolized anthrax attack. The protective mechanisms should be a combination of pre- and post-exposure options. First, each federal organization should not just identify what mission essential functions they need to do during a crisis; the organization should be asking itself what additional functions need to be conducted in the days and weeks immediately after the event. The organizations need to determine the “who” and the “how” these functions will be reestablished. Depending on the outcomes, the organization can tailor its plan by following these recommended courses of action.

Presently, pre-event anthrax prophylaxis is not offered to the NCR Federal workforce and AVA is not licensed to protect Federal workers unless they are in a designated high-risk group for an anthrax attack, such as the military. Mission essential personnel, to include COOP designees, should be offered AVA on a voluntary or mandatory basis as the most at-risk personnel. This action needs to start immediately as approvals are going to be required, to include the FDA. Other Federal workers should be offered the AVA once the emergency essential personnel are vaccinated.

Besides the benefit of workforce protection, AVA can be furnished from the SNS. Using SNS AVA that is nearing the limits of its shelf-life would limit the loss due to the vaccine reaching its expiration date. This arrangement would protect lives and save the taxpayers



money. An additional benefit, although somewhat contentious, would be more population-based data on AVA's use and effects other than what is presently gained from military studies.

Post-exposure antibiotics require a methodology that incorporates several alternative strategies to maximize protection that is independent of whether the AVA was given.

Recommend mass prophylaxis mechanisms always include all family members who reside with the Federal employee determining the amount to dispense. This alleviates concerns that the Federal employees will always have about the protection of their families and it will also ease some of the dispensing burden off the local jurisdictions' PODs.

Institute a program that authorizes home-based prophylaxis using the antibiotics cipro and doxy. The potential exists for Federal workers to be at home when the decision to mass prophylaxis occurs even though the exposure happened during normal work hours. Emergency essential personnel are more likely to return to their place of duty having begun their antibiotic regimen as these individuals need to go to a designated worksite. If the employee and the family begin their antibiotics, any worries about being exposed can be overcome. Initially, recommend offering all NCR Federal employees the ability to purchase a five-day antibiotic regimen for themselves and members of their household similar to the concept used in the MedKit Study. Eventually, the program could be integrated with the SNS much like the AVA described above to allow product that is in the last few years before its expiration date to be distributed to NCR Federal employees to replace the initial purchased antibiotics. The program would perpetuate with no further cost to the Federal employee.

Even though the home-based prophylaxis will protect some NCR Federal employees, many may be at their place of work when the decision is made. If this is the case, a mechanism must exist to provide prophylaxis to those individuals in an expedited manner.

The Federal Points of Dispensing concept would expediently provide mass prophylaxis to the NCR federal workforce as long as personnel are at their workplace and the antibiotics are pushed quickly enough to make a federal POD a feasible dispensing option. Some additional options that need to be considered are: collocating antibiotics for federal PODs at the closest push package location or another location near the NCR so they can be quickly delivered for dispensing; making federal PODs with an assigned sector of support instead of organizational; pre-identify locations as mega-federal PODs to serve Federal employees no matter what organization they are affiliated with and they could be located near major thoroughfares; or any combination of these. Evaluation and refinement of these federal POD options is necessary to ensure full area coverage and minimize the inefficiencies due to the lack of prior mass prophylaxis planning.

In closing, the NCR Federal employees are the force behind the USG's ability to respond to and recover from an aerosolized anthrax attack. In order to limit fatalities and expedite the return to normal government operations, a risk-based, multi-pronged approach is the only way to ensure success. Mechanisms need to be established to protect this workforce and their families as soon as possible.

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<sup>39</sup> Ibid, slides 5-6.

<sup>40</sup> United States Army Medical Materiel Agency, "Extending the Shelf Life of Critical "War Reserves" Medical Materiel Using the FDA/DOD Shelf Life Extension Program," U.S. Department of the Army, available from [www.usamma.army.mil/documents/SLEPInfoPaper-Mar2005.pdf](http://www.usamma.army.mil/documents/SLEPInfoPaper-Mar2005.pdf) , 1-3, Internet accessed 10 December 2007.

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